

K08055

Pg 1 of 3

8

Section II

510(k) SUMMARY

MAR - 6 2008

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:

Date	January 21, 2008
Submitter	Intuitive Surgical, Inc. 950 Kifer Road Sunnyvale, CA 94086
ER Number	2955842
Contact	Michael Yramategui Sr. Director, Regulatory Affairs Telephone: (408) 523 - 2145 Fax: (408) 523 - 1390 E-mail: mike.yramategui@intusurg.com
Subject	<u>Trade Name(s):</u>
Device	8.5mm 3D Stereo Endoscope
	<u>Classification Name:</u>
	Endoscope and Accessories (21 CFR 876.1500) Rigid Endoscope (21 CFR 876.1500) Gynecologic Laparoscope / Accessories (21 CFR 884.1720)
	<u>Common Name:</u>
	3-D Endoscope and Accessories
	<u>Device Class:</u>
	Class II, GCJ, Laparoscope, General & Plastic Surgery
Predicate Devices	12mm 3D Stereo Endoscope (FDA clearance under K001666)

Device Description	<p>This Special 510(k) is being submitted to include an additional 8.5mm sized 3D Stereo Endoscope as an additional accessory model to the currently cleared 12mm 3D Stereo Endoscope. Both endoscopic models are for use with the Intuitive Surgical® Stereo View Endoscopic System and Intuitive Surgical <i>da Vinci</i>® and <i>da Vinci</i>® S™ Surgical Systems.</p> <p>The 8.5mm 3D Stereo Endoscope was developed to provide an option for use of a smaller patient access port than the currently cleared 12mm 3D Stereo Endoscope, while maintaining stereo view capabilities.</p> <p>There are no changes in the basic design, technology, materials or manufacturing processes for the 8.5mm Endoscope. The intended use for the subject device in conjunction with the Intuitive Surgical® Stereo View Endoscopic System (i.e., cameras, illumination sources, video processing equipment) is identical to the previously cleared intended use for the 12mm Endoscope in conjunction with the Intuitive Surgical® Stereo View Endoscopic System.</p>
Intended Use	<p>The Intuitive Surgical® Stereo View Endoscopic System is intended for endoscopic viewing of internal surgery sites during minimally invasive surgery in the peritoneal cavity, thoracic cavity, and peritoneum. It is designed for use with the Intuitive Surgical® Endoscopic Instrument Control system during laparoscopic and thoracoscopic surgical procedures.</p>
Comparison to Predicate Device	<p>The basic design and function of the subject 8.5mm Endoscope in conjunction with the Intuitive Surgical® Stereo View Endoscopic System is identical to the predicate system, except that an 8.5mm Endoscope is an available option to the 12mm Endoscope currently cleared. The reduced diameter shaft of the endoscope is also shorter in length, but there are no changes in the compatibility of the 8.5mm Endoscope with the cameras, illumination sources or other components of the video processing system. It is built by the same manufacturer as the 12mm endoscope, with the same materials and manufacturing processes.</p>

Technological Characteristics	The technological characteristics of the subject device are identical to the predicate device.
Performance Data	Design analysis and comparison, as well as bench testing, have been conducted to confirm that basic functional characteristics of the subject device are substantially equivalent to the predicate device cited, and that design output meets the design input requirements.
Conclusion	Based upon the technical information, intended use and performance information provided in this Special 510(k), the 8.5mm 3D Stereo Endoscope) described herein has been shown to be substantially equivalent to current legally marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Intuitive Surgical, Inc.
% Mr. Michael H. Yramategui
VP of Clinical and Regulatory
Affairs
950 Kifer Road
Sunnyvale, California 94086

MAR - 6 2008

Re: K080155

Trade/Device Name: Intuitive Surgical® Stereo View Endoscopic System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 21, 2008
Received: February 22, 2008

Dear Mr. Yramategui:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – Mr. Michael H. Yramategui

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080155 pg 1 of 11

Section III

Indications for Use

510(k) Number (if known):

Device Name: *Intuitive Surgical*[®] Stereo View Endoscopic System

Indications For Use:

The Intuitive Surgical[®] Stereo View Endoscopic System is intended for endoscopic viewing of internal surgery sites during minimally invasive surgery in the peritoneal cavity, thoracic cavity, and peritoneum. It is designed for use with the Intuitive Surgical[®] Endoscopic Instrument Control system during laparoscopic and thoracoscopic surgical procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Neil R. Syl for xxxx
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080155